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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,079	01/21/2000	Patricia A. Billing-Medel	6451.US.P	5338

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/489,079	Applicant(s) BILLING-MEDEL ET AL.	
	Examiner Janet Epps	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 52-81 is/are pending in the application.
- 4a) Of the above claim(s) 62-69 and 71-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-61, 70 and 77-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 52-61, 70, and 77-81, drawn to the elected invention in Paper # 7, are currently under examination.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-11-02 has been entered.

### ***Drawings***

3. Applicants have not responded to the objections to the Drawings set forth in the PTO-948 attached to the Official Action mailed 10-24-2000. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

### ***Response to Arguments***

4. Claims 52-61, 70, and 77-81 remain rejected under 35 USC § 101 and 112, first paragraph, for the reasons of record set forth in the Official Action mailed 10-24-2000, in the rejection of claims 23-25, 28-29, 36-37, 39-40, and 51 under 35 USC 101 and 35 USC 112, first paragraph.

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Applicant's arguments filed 3-11-02 have been fully considered but they are not fully persuasive. Applicants traverse the instant rejection on the grounds that BS322 and NY-BR-1 are the same molecule, as evidenced by Exhibit A which shows the homology between BS322 and NY-BR-1. However, the sequence alignment between NY-BR-1 and BS322, does not indicate what corresponding sequence of BS322 was actually used to produce the alignment shown in Exhibit A. Moreover, it appears that the NY-BR-1 sequence is 4408 nucleotides in length, however the query sequence (assuming it represents a BS322 sequence) matches only 1143 nucleotides of the total 4408 nucleotides of NY-BR-1, indicating only about a 25% identity over the full length sequence of NY-BR-1. Additionally, it is noted that the subject of the instant claims are the isolated polypeptides having at least 95% identity over the length of a sequence according to SEQ ID NO: 25-28. These polypeptides range in length from 38-317 amino acids. However, the protein sequence of NY-BR-1 consists of 1341 amino acids. Applicants have not provided a comparison between the sequences according to SEQ ID NO: 25-28 and the amino acid sequence of NY-BR-1. Applicants have not provided sufficient evidence that the isolated polypeptides according to SEQ ID NO: 25-28 are equivalent to the NY-BR-1 breast cancer antigen polypeptide.

5. Claims 52-61 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record in the Office Action of 9-04-01.

Applicant's arguments filed 3-11-02 have been fully considered but they are not fully persuasive. Applicants traverse the instant rejection on the grounds that the prior art provides

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methods for identifying proteins having 95% homology to the sequences of the present invention. However, Applicants are enabled to identify polypeptides having 95% homology to the polypeptides of the present invention, this method does not provide an adequate description of the actual amino acid structure of the full breadth of polypeptides encompassed by the claimed invention. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between the genus members are permitted, and neither the specification nor the claims provide any guidance as to what specific changes should be made.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state that:

"To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

As stated in the guidelines above "[a]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." It is noted that the guidelines does not mention that the availability of a method to isolate the claimed invention is sufficient to indicate that Applicants were actually in possession of the claimed invention at the time of filing. The guidelines indicate that in order to adequately describe a claimed invention, "descriptive means as words, structures, figures, diagrams, and

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formulas” are needed. Therefore, reference to a potential method to isolate the polypeptides of the present invention having at least 95% identity over the full length sequence of SEQ ID NO: 25-28 is not sufficient to describe the claimed genus of polypeptides.

6. Claims 62-69, 72-76 and 80 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 3-11-02 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds by way of providing evidence that methods for identifying epitopes in a novel peptide sequence are well known and described in both the scientific, commercial, and patent literature. However, Applicants have not did not provide an adequate response to this rejection, other than to address the "epitope" language. The rejection is maintained since it remains that the isolated polypeptides according to SEQ ID NO: 25-28 are not isolated polynucleotides or DNA molecules. Applicants have not appropriately addressed this issue.

### *Conclusion*

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
May 10, 2002



SEAN MCGARRY  
PRIMARY EXAMINER  
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